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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,359	04/16/2004	Peter Gibson	22409-00107-US	8104
30678 7590 04/27/2009 CONNOLLY BOVE LODGE & HUTZ LLP 1875 EYE STREET, N.W. SUITE 1100 WASHINGTON, DC 20006				
EXAMINER				
HOLMES, REX R				
ART UNIT		PAPER NUMBER		
3762				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/825,359

Applicant(s)

GIBSON, PETER

Examiner

REX HOLMES

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-9, 14, 20-24, 27, 28, 30, 31 and 89-118 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-9, 14, 20-24, 27-28, 30-31, 89-118 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-2, 4-9, 14, 20-24, 27-28, 30-31 and 89-92 are rejected under 35 U.S.C.

112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 states, "without manual insertion" in lines 5-6 of the claim, "without manual insertion" is not described in the original disclosure, in combination with the other steps or elements in the claim, and it is considered a negative limitation/exclusionary proviso because it precludes other elements/steps. Any claim containing a negative limitation or exclusionary proviso, which does not have basis in the original disclosure, should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. MPEP 2173.05(i). Although the specification provides support for "preferably not inserted or screwed into the bony surface", it does not provide support for "without manual insertion".

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 1-2, 4, 7-9, 14, 20, 24, 27-28, 30-31, 89-93, 98-100, 104-107 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Independent claims 1 and 93 state that protuberance is configured to attach to the patient's bone without manual insertion. This is vague as it is unclear what the applicant means by manual assistance, as the protuberances have to be manually inserted within the periosteal pocket against the bone in order for the protuberances to contact the bone to allow for osseointegration (see ¶150).

Claim Rejections - 35 USC § 102/103

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-2, 4, 7-9, 14, 20, 24, 27-28, 30-31, 89-92, 108-110, 113-114 are rejected under 35 U.S.C. 102(b) as being anticipated by Berrang et al. (U.S. Pub.

2002/0019669 hereinafter "Berrang") or, in the alternative, under 35 U.S.C. 103(a) as obvious over Berrang.

8. Berrang discloses a hearing aid/cochlear apparatus that comprises a housing adapted to abut the patient's bone (Figure 6). Berrang further discloses that the housing can be made out of ceramic (¶¶ 23, 25), and includes components located within the housing (2), and an osseointegrating protuberance that extends from the housing into the bone (¶ 22). Berrang further discloses that the device is a tissue-stimulating device (Figs. 1-6; ¶ 77).

9. It is noted that osseointegration occurs naturally between titanium and bone.

10. Berrang discloses that the implantable device is configured, to be secured to the mastoid portion of the temporal bone in the tissue surrounding the skull (Fig. 3-6). Berrang further discloses that the fixation device is a threaded screw and is capable of being removed after osseointegration (¶ 22).

11. Regarding claim 106, Berrang further discloses that the housing is coated with a medical grade silicone (¶ 69).

12. Regarding claims 108-110, Examiner notes the limitation "configured to be placed in direct contact with but not within the bone and further configured to gradually sink into the bone during osseointegration of said protuberance", is only functional language and only requires the capability to so perform. Here the titanium screws are capable of being positioned adjacent the bone and are further capable of sinking into the bone during osseointegration.

13. In the alternative, Berrang discloses that it has a housing made out of ceramic and protuberances made out of titanium, but Berrang fails to disclose that ceramic is non-osseointegrating and titanium is osseointegrating. However, the Applicant's specification discloses that ceramic is a non-osseointegrating material and that titanium is an osseointegrating material (Applicants Spec. ¶35). Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have used the device to allow for replacement of the device while still allowing for osseointegration of the screws, as it was known in the art that titanium promotes bone growth and ceramics do not promote bone growth.

14. Claims 5-6, 21-23 and 112-113, 115-118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berrang as applied to claims 1, 93 and 98 above, and further in view of Håkansson (U.S. Pat. 6,840,919).

15. Regarding claims 5-6, 21-23 and 112-113, Berrang discloses the claimed invention as described in detail above, except for the elongated flanges that hold the disposed protuberances at opposing angles. Håkansson teaches that it is known to use flanges and anchoring devices that are disposed at an opposing angle that is approximately 45-85 degrees and in the same plane as set forth in Figures 1 and 2 to provide anchoring means for the implantable device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the hearing aid as taught by Berrang, with flanges and multiple anchors disposed in the flanges at opposing angles as taught by Håkansson, since such a modification would provide the

predictable results of a hearing aid with strong anchoring means for providing increased hold and more surface area for osseointegration.

Response to Arguments

16. Applicant's arguments with respect to claims arguments filed 3/25/08 have been fully considered but they are not persuasive.

17. Regarding the rejection of claims 1-2, 4, 7-9, 14, 20, 24, 27-28, 30-31, 89-92, 108-110, 113-114, applicant argues that Berrang fails to disclose a protuberance that is configured to attach to the patient without manual insertion. It is noted that the limitation, "configured to attach to the patient without manual insertion" is functional language and only requires the capability to so perform. In this case the protuberances of Berrang could be placed against the skull without manual insertion and since the protuberances allow for osseointegration they are capable of attaching to the patient without manual insertion.

18. The applicant further argues that the examiner failed to address the arguments previously presented regarding claim 108. The examiner cited prior art in action sent on 10/6/08 and has included it again in this action regarding the osseointegrating properties of titanium. The prior art of record is listed in the conclusion section of this action and the conclusion section of the action sent on 10/6/08.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Berrang et al. (U.S. Pat. 6,516,228), De Rowe (U.S. Pat.

6,042,380), Dugot (U.S. Pat. 5,738,521), Gilman (U.S. Pat. 5,176,620), Jeffcoat et al. (4,333,469) – All discuss the bone growth properties of titanium.

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REX HOLMES whose telephone number is (571)272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. H./
Examiner, Art Unit 3762

/George R Evanisko/
Primary Examiner, Art Unit 3762